



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,229	04/12/2001	Suad Efendic	X-10822A	4450

25885 7590 07/23/2003

ELI LILLY AND COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 07/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/834,229

Applicant(s)
EFENDIC

Examiner
Christine Saoud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 14, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-20 and 22-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 13 and 18 have been amended, claims 22-26 have been added and claim 21 has been canceled as requested in the amendment of paper #11, filed 14 May 2003. Claims 13-20, 22-26 are pending in the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 14 May 2003 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 112

5. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in paper #10.

Applicant argues that the basis for peptides is disclosed throughout the specification (see response at page 4). However, although "peptides" are mentioned in the specification, the concept of a method using "a peptide that enhances insulin sensitivity by interacting with the same receptor or receptors with which GLP-1, GLP-1 analogs and GLP-1 derivatives interact" is not present in the instant specification and is new matter for the reasons of record. Briefly, there is no basis for the narrower recitation "peptide", and this is a different inventive concept from the originally presented "compound" of the instant specification. The broadest reasonable interpretation of "peptide" would mean any peptide molecule, regardless of amino acid structure, which exerted the activity in the instant claims. This includes any peptide, regardless of its structural relationship to GLP-1. This concept does not find support in the specification as originally filed, and the new matter rejection is maintained.

Claim 21 is also rejected for lack of an adequate written description. The claims are directed to a method of reducing morbidity and mortality after myocardial infarction by administering a "peptide that enhances insulin sensitivity by interacting with the same receptor or receptors with which GLP-1, GLP-1 analogs and GLP-1 derivatives interact". However, the instant specification only provides for peptides which are related to GLP-1 in that the peptides are GLP-1, GLP-1 analogs and/or GLP-1 derivatives. The broader recitation of "peptides" is not supported in the instant specification as filed because there are no examples of peptides which are not related to GLP-1, and therefore, there is no associated structure with the recitation of "peptides", only a function recited in the claims. Applicant argues that the "specification discloses thousands of peptides that interact with the GLP-1 receptor beginning at page 5 of the

specification". However, a review of the instant specification only appears to reveal molecules which are derived from GLP-1 (i.e. GLP-1 analogs, variants and derivatives). In so far as the claims encompass any peptide which has the recited activity, this is similar to a single means claim in that the claim encompasses any molecule with a particular activity (in this case, any peptide). This type of claim is unsearchable as there is no specific structure which is provided in the claim. There may be peptides which are in use for treatment of MI which have the claimed activity, but the art may not disclose this activity. This cannot be searched because the claims fail to recite any structure. Additionally, the instant specification fails to describe these peptides such that the skilled artisan would readily recognize them as part of the claimed invention. Applicant further argues that one could screen for peptides with the recited activity, however, this is not a written description of those molecules. A method of isolating a particular molecule is not a proper written description of the molecule, and therefore, is not a proper written description of the claimed method and the rejection is maintained.

Double Patenting

6. Claims 13-19 (and newly submitted claims 22-26) are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,277,819 for the reasons of record in paper #10. Applicant has not argued this rejection, and it is therefore, maintained.

Conclusion

7. No claim is allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**